

REMARKS

Status of Claims

Claims 1-18 are pending in the application and rejected. Claims 1-18 are rejected. Claims have been amended. Support for the amendments can be found in the specification as originally filed. New claims 19-31 have been added. No new matter has been added.

Double Patenting

Claims 1-18 are subject to an obviousness-type double patenting rejection as being unpatentable over claims 1-5 of U.S. Patent No. 6,628,990. Applicant has filed a terminal disclaimer herewith and believes this obviates the double patenting rejection.

Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-18 under 35 U.S.C. §103(a) over Edwards et al. '441 ("Edwards I") in view of Edwards '906 ("Edwards II") and further in view of Swanson '760. The Examiner states that regarding claims 1, 3, 5, 6, 8, 9 and 12-14, Edwards I discloses the claimed subject matter but does not disclose that the method is used to reduce bleeding and/or blood loss. The Examiner also states that Edwards I fails to disclose making an incision into the tissue which has been heated. The Examiner then states that Edwards II discloses a tissue heating device having retractable needles and teaches the alleged equivalent energy delivery of microwave with cooling means. Lastly, the Examiner states that Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss. Having completed the theoretical combination, the Examiner states that therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards I, as further taught by Edwards II, and finally as taught by Swanson '760, i.e. to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue. The Examiner then rejected claims 7, 10 and 11 as being unpatentable over Edward I in view of Edwards II and further in view of Swanson '760. Applicant traverses the rejection and respectfully requests reconsideration.

In making the obviousness rejection, Applicant respectfully suggests that the Examiner has not established a *prima facie* case of obviousness. To establish *prima facie* obviousness,

“there must be some suggestion or motivation . . . to modify the reference.” MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). “The . . . suggestion [to combine] . . . must . . . be found in the prior art, and not [be] based on applicant’s disclosure.” *Id.* Further, while there are three possible sources for a motivation to combine references, i.e. the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art, the level of skill in the art cannot be relied upon to provide the *suggestion* to combine references. MPEP §2143.01 citing *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

Establishing that the claimed invention is an obvious modification of the prior art reference requires the Examiner to develop an evidentiary basis for the obviousness finding. *In re Lee*, 277 F.3d 1338, 1345-1346, 61 USPQ2d 1430, 1435-1436 (Fed. Cir. 2002). In *Lee*, the Federal Circuit reversed a finding by the Board of Appeals that an invention was obvious over the prior art because the Board failed to establish an evidentiary record on which to substantiate the finding of obviousness. The Board had held that it was not necessary to present a source of the teaching, suggestion, or motivation to combine these references or their teachings, and adopted the Examiner’s obviousness rejection that the combination of two prior art references cited during prosecution “would have been obvious to one of ordinary skill in the art” without further discussion of how it was obvious. *Id.* at 1341, 1344, 61 USPQ2d at 1432, 1434. The Federal Circuit found that the Board *erred* when it further stated that “a specific hint or suggestion of motivation to combine was not required,” and that “[t]he conclusion of obviousness may be made from common knowledge and common sense a person of ordinary skill in the art without any specific hint or suggestion in the particular reference.” *Id.* at 1341, 61 USPQ2d at 1432. The Federal Circuit then held that the Examiner must particularly mention some suggestion or motivation in the reference regarding the desirability of making the modification. *Id.* at 1345-1346, 61 USPQ2d at 1435.

Similar to the prosecution of the application in *Lee*, Applicant respectfully suggests that the Examiner has failed to establish an evidentiary record on which to substantiate the finding of obviousness because neither Edwards I, nor Edwards II, nor Swanson ‘460 disclose, teach or

suggest the modification being proposed by the Examiner. Absent such a suggestion, the references cannot be combined. *See Id.* at 1343, 61 USPQ2d at 1433.

Edwards I teaches the reduction of tissue mass in the vicinity of an electrode that comprises a stylet. The Edwards stylet has a retractable sleeve portion that when retracted exposes only the stylet tip. The sleeve portion, made from an insulating plastic material, surrounds the electrode and serves to protect surrounding tissue when the electrode is energized, the delivery of energy thus being confined to the tip that has been inserted into the tissue mass to be ablated. The Examiner acknowledges that Edwards fails to disclose the step of making an incision into the tissue which has been ablated. Applicant wishes to point out to the Examiner that when tissue is ablated it does not necessarily need to be removed and thus Edwards I does not teach making an incision or resecting the tissue as acknowledged by the Examiner. Moreover, Edwards I does not teach or suggest “advancing the applicator along the planned incision line, extending the tissue-piercing distal tips of said array of needles into the volume of tissue to be resected along the planned incision line” or “resecting the volume of tissue” as claimed by Applicant in claim 1 or “extending the tissue-piercing means of said array of needles to a desired depth of a volume of the tissue to be treated” and “resecting the tissue from the body” as claimed by Applicant in claim 3.

The Examiner states that Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss. However, Swanson discloses a blunt-tipped probe that is placed on or adjacent tissue to deliver energy. See, e.g. FIG. 71A. The probe of Swanson is not advanced into and does not pierce the tissue to be treated. Swanson discloses:

A surgical method in accordance with a present invention may be used to reduce the level of bleeding during surgical procedures. The method generally comprises the steps of coagulating (or ablating) tissue to a predetermined depth and then forming an incision in the coagulated tissue. The coagulation can be accomplished by applying RF energy with, for example, the probe shown in FIG. 71a. Because the tissue is coagulated, the incision will not result in bleeding.

One exemplary procedure employing the present method is the removal of a diseased liver lobe. This [is] a relatively time consuming procedure and, using conventional surgical techniques, there is a significant risk of serious

bleeding. In accordance with one embodiment of the present invention, tissue in the lobe is coagulated to a depth of approximately 3 mm to 7 mm using RF energy. The coagulated tissue is then cut and separated with a scalpel, electro-surgical device, or other suitable instrument. To avoid bleeding, the depth of the cut should not exceed the depth of the coagulated tissue. The process of coagulating tissue and then forming an incision in the coagulated tissue can be repeated until the incision reaches the desired depth. Here, each coagulation and incision cycle will take approximately 90 seconds, 60 seconds to perform the coagulation and 30 seconds to perform the incision.

The present surgical technique is, of course, applicable to surgical procedures in addition to the removal of a liver lobe. Such procedures may, for example, involve the spleen, the kidneys, other areas of the liver, the heart, skeletal muscle, the lungs (such as a pulmonary lobotomy) and the brain. The present technique is also useful in oncological surgical procedures because cancerous tumors tend to be highly vascularized. One exemplary oncological procedure is the de-bulking of a cancerous tumor.

A surgical tool set in accordance with a present invention includes, among the other tools needed for a particular procedure, a device for coagulating soft tissue and a device for cutting the tissue. Suitable devices for coagulating soft tissue are illustrated for example, in FIGS. 62-88 and 95-101. With respect to the probe shown in FIGS. 71f and 71g, the portion of the probe which includes the second connector portion 321, the shaft 310 and a plurality of electrode elements can be included in the tool set with or without the handle 312". As noted above, scalpels (such as the scalpel 375 in FIG. 102), electro-surgical devices and other suitable instruments may be used to cut tissue. Preferably, as illustrated for example in FIG. 102, the tool set is housed in a sterile package 377 that has a flat rigid bottom portion and a top transparent top cover 379 that provides recesses for the tools, thereby providing a ready to use surgical kit. The bottom portion may be formed from TYVEK spun bonded plastic fibers, or other suitable materials, which allow the contents of the package to be sterilized after the tools are sealed within the package.

Col. 45, line 19 to col. 46, line 5

None of the embodiments of probes suggested by Swanson include a probe that pierces tissue for one simple reason, namely advancing tissue-piercing needles into tissue would cause the excessive bleeding that Swanson teaches is desirable to avoid. Therefore, Swanson teaches away from using needles with tissue-piercing means and advancing the tissue-piercing means into tissue as claimed by Applicant in claims 1 and 3 because Swanson teaches using a blunt probe that is placed on the tissue, not into the tissue and certainly not in tissue-piercing engagement. Because Swanson discourages the modification suggested by the Examiner, Swanson cannot be combined with Edwards.

Further Swanson does not teach advancing its probe to a desired depth in order to make an incision as claimed by Applicant in claim 3. Swanson teaches coagulating tissue with the probe placed on the tissue, and then making an incision in the coagulated tissue to no more than the depth that the electromagnetic energy reached, otherwise excessive bleeding will occur. Then Swanson teaches again placing the probe on tissue and coagulating the tissue again and making an incision in the coagulated tissue to no more than the depth that the electromagnetic energy reached, otherwise excessive bleeding will occur, and so on and so on until the desired depth of incision is achieved. This repetition is the antithesis of Applicant's invention. Applicant inserts its tissue piercing needles to the desired depth of penetration, energy is applied and then an incision is made into the desired depth.

The Examiner seeks to combine Swanson with Edwards I stating that one skilled in the art at the time Applicant's invention was made would be motivated to combine Swanson and Edwards I. Applicant finds no such suggestion and respectfully requests that if the Examiner maintains his rejection, he point to the column and line number of Swanson where "tissue-piercing distal tips of needles" or "tissue piercing means" are suggested. Similarly, Applicant respectfully requests that the Examiner point to the column and line number of Edwards I where Edwards suggests that his invention can be used to make an incision along a planned incision line.

Applicant respectfully suggests that claims 1 and 3 are allowable over the art of record and because the dependent claims depend from allowable base claims, Applicant respectfully suggest that they too are allowable.

New Claims

Applicant has added new claims 19-31 in order to more fully claim the scope of its invention. Because claims 19-31 depend from an allowable base claim, Applicant suggests they too are allowable and respectfully request allowance.

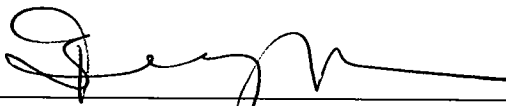
Conclusion

Applicant has made a significant contribution to the art of surgery and allowance of all claims is respectfully requested. If the Examiner believes that a teleconference would be of value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below. Applicant hereby petitions for a three-month extension of time, the statutory period for response having expired on January 5, 2007 and this response being filed on or before the three-month extension period of April 5, 2007. Applicant hereby authorizes the Commissioner to charge the three-month extension of time fee, or additional fees or overpayment, to Deposit Account No. 50-1901 (Reference #22413-14).

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Respectfully submitted,

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